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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,481	03/05/2001	Frank Hulstaert	11362.0034.P	8708

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EXAMINER
STANDLEY, STEVEN H

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,481	HULSTAERT ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/31/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,8,11 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,11 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/31/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to amendment

1. The amendment filed on 1/31/05 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 5, 8, 11, 18, 19, and 20 rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 1 and 18 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in the reply filed 12/14/04. In that paper, applicant has stated that "'total tau' of the instantly claimed invention includes tau in the size range of 48-65 kD [page 6, lines 7-9]," and this statement indicates that the invention is different from what is defined in the claim(s) because page 23, lines 6-8 define the total tau measured as "both normal and hyperphosphorylated." It is entirely unclear what applicant is claiming. Moreover, it is not clear whether applicant means "total tau" in the sample as measuring the total amount of all tau present in the sample or whether applicant means sampling the total types of normal and hyperphosphorylated tau.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 8, 11, 18, 19, and 20 are rejected under 35 U.S.C. 102(b) for reasons made of record in the office action mailed 12/14/04 at pages 2-3.

3. Applicant has traversed the examiner's rejection of claims 1, 5, 8, 11, 18, 19, and 20, in the amendment filed on 1/31/05, under 35 U.S.C. 102(e) as being anticipated by US 6797478 B1 (9/28/04), Zemlan & Campbell. Applicant's arguments have been considered and found to be nonpersuasive for the reasons made of record and the reasons set forth below.

Applicant argues on page 5 of the amendment filed on 1/31/05 that "the currently amended claims require an analysis of the levels of total tau whereas the invention described in the '478 patent is explicitly limited to an analysis of the level of "truncated" tau." Applicant further cites a passage from the '478 patent (col 12, lines 1-4, 38 and 39) wherein CSF has been probed and found not to contain significant amounts of full-length tau. Contrary to Applicant's assertions however, the prior art could not have held that full-length tau was not present in significant amounts in the CSF, if it had not probed for it as well as fragments of tau. Therefore, '478 teaches 'total tau' as recited by the applicant. In further support of this, applicant is invited to examine Figure 4 of

'478, which is a high–contrast picture of an immunoblot of CSF with anti-Tau antibodies. The most significant signal is indeed within the range of 55 ± 5 kD to 15 ± 5 kD, which is reasonably composed mostly of tau fragments, however any full-length in the CSF sample is present on the blot, interacts with the antibody used and gives a signal according to it's abundance. In support of this, an antibody from that panel (cTAU12) also recognizes full-length *recombinant* tau (see Figure 2 of '478), indicating the antibody was fully capable of measuring full-length tau as well as other fragments. This further indicates that the art has taught measuring full-length tau in addition to fragments which together constitute "total tau."

On the other hand, applicant argues that the support for measuring full-length tau as well as fragments which constitute "total tau" comes from page 23, lines 6-8 (emphasis added) of the specification which discloses that "CSF-tau levels were determined using a sandwich ELISA...that measured *total tau* (*both normal and hyperphosphorylated tau*)." The examiner reasonably interprets this to mean that by total, the specification means "normal and hyperphosphorylated," of which both types are disclosed as measured in '478 (col 2, lines 50-65). The specification is silent with respect to particularly measuring fragments or measuring full-length tau as they constitute part of total tau.

It is further noted that the limitations of claim 5, directed to a method of claim 18 in which the cns damage is caused by a benign or malignant primary brain tumor, are met in '478 in the abstract, and also in column 3, lines 1-20, wherein diagnosing CNS damage due to brain tumors is disclosed.

Conclusion

4. The rejection of claims 1, 5, 8, 11, and 18-20 under 35 U.S.C. 102 (e) is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven H. Standley whose telephone number is (571) 272-3432. The examiner can normally be reached on 8:00-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Steven Standley, Ph.D. 5/30/05

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER